

34. (New) The compound of claim 3, wherein said ECL label is different from said ECL coreactant.

### REMARKS

The amended claims 3 and 4 are fully supported in the disclosure, see specification pages 10-11. The new claims are fully supported by the disclosure on pages 4,5, 10-11 and 17 of the specification. An IDS and a new Oath or Declaration will be submitted in a supplemental communication.

#### I. Status of the Application

The Examiner states that the arguments presented in the Preliminary Amendment mailed January 26, 2001 (submitted with the filing of the present continuation application) “have not been considered as they pertain to a previous application that is not under examination (08/936,971 was abandoned on September 21, 2000) i.e., a response to a Final Action is NOT PROPER at this point in the litigation” (Official Action, page 2).

The Examiner’s refusal to consider and respond to Applicant’s arguments set forth in their Preliminary Amendment is improper. Applicants prepared and submitted the Preliminary Amendment to address rejections raised in the parent application and to further the prosecution of the present continuation application. As stated in the MPEP:

Where the requirements are traversed, or suspension thereof requested, the examiner should make proper reference thereto in his or her action on the amendment. **Where the applicant traverses any rejection, the examiner should, if he or she repeats the rejection, take note of the applicant's argument and answer the substance of it.** If a rejection of record is to be applied to a new or amended claim, specific identification of that ground of rejection, as by citation of the paragraph in the former Office letter in which the rejection was originally stated, should be given.

[MPEP § 707.07(f), emphasis added].

Several rejections made in the parent application, Serial No. 08/936,971, were repeated in the most recent Official Action issued in the present continuation application. Applicants submit that the Examiner's failure to provide any rebuttal to the arguments raised in Applicant's Preliminary Amendment (January 26, 2001) with respect to these rejections is improper. The MPEP states that "Piecemeal examination should be avoided as much as possible" (MPEP § 707.07(g)). Accordingly, Applicants request that the next Official Action (if any further official action is issued) be non-final since Applicants previous response was not properly considered or rebutted in the present Official Action.

## **II. Priority Claim.**

Applicants thank the Examiner for pointing out the discrepancy in the claim of priority as compared to the parent case. As suggested by the Examiner, the claim of priority has been amended to match the amendment in the parent case.

Applicants submit that claims 9, 11 and 14-16 are supported by parent case U.S.S.N. 08/936,971, and apparently not supported by the disclosures of the other priority applications. However, claim 17 is fully supported by the disclosure of U.S.S.N. 08/484,766 on page 6, lines 9-15.

## **III. Figure 1 is objected to for containing minor imperfections.**

Submitted herewith is a corrected drawing of Figure 1 ("Scheme for the synthesis of Ru-tag/TM Conjugates") showing the appropriate single bonds between the pyridine rings to complete the bipyridine ligand structures.

## **IV. Claims 3, 4, 9-22 and now new claims 26-34 are pending in this application. The Examiner, as set forth below, rejects claims 3, 4 and 9-22.**

The Applicants thank the Examiner for rejoining Group I (claims 3-4) with Group V (claims 9-12).

- a) Claims 3, 4 and 9-22 are rejected under 35 U.S.C. § 112, first paragraph (written description requirement);
- b) Claims 3, 4 and 9-22 are rejected under 35 U.S.C. § 112, first paragraph (enablement requirement);
- c) Claims 3, 4 and 9-22 are rejected under 35 U.S.C. § 112, second paragraph;
- d) Claims 3-4, 10, 12-13 and 18-22 are rejected under 35 U.S.C. § 102(a) as allegedly anticipated by Liang et al.;
- e) Claims 3, 11, 13 and 14 are rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Faulkner LR;
- f) Claims 3-4, 10-14 and 19-22 are rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Massey et al. (WO 87/06706);
- g) Claims 3-4, 10-14 and 19-22 are rejected under 35 U.S.C. § 102(e) as allegedly anticipated by Massey et al. (U.S. Patent 5,591,581);
- h) Claims 3-4, 10-14 and 19-22 are rejected under 35 U.S.C. §§102(f) and 102(g) as allegedly anticipated by Massey et al. (U.S. Patent 5,591,581); and
- i) Claims 3-4, 9-17, 19 and 21-22 are rejected under 35 U.S.C. § 103(a) as allegedly been obvious over Knight et al in view of Faulkner LR.

Applicants respectfully traverse each of the above-identified rejections for the reasons set forth below:

**a. Claims 3-4 and 9-22 fully comply with written description requirement of 35 U.S.C. § 112, first paragraph.**

In the Official Action, the Examiner asserts that the claims are allegedly “not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the

inventor(s), at the time the application was filed, had possession of the claimed invention”

(Official Action, page 8).

More specifically, the Examiner alleges that: “applicants have not provided enough examples to demonstrate that they are in possession of the full scope of the invention as claimed” and that the “claims would also encompass energy-deficient systems” (Official Action, pages 8-9). Applicants respectfully traverse.

First, contrary to the Examiner’s suggestion, the claims cannot encompass “energy-deficient systems” or non-functional ECL emitter/coreactant pairs since the claims are limited to a compound which “emits electrochemiluminescence when exposed to electrochemical energy” (e.g., claim 3). Therefore, the claims explicitly exclude compounds, which are “energy-deficient” or do not produce ECL.

Second, the absence of “enough examples” is not relevant to a determination of compliance with the “written description requirement” of the first paragraph of 35 U.S.C. § 112. (MPEP § 2163). Examples are not required.

Moreover, Applicants submit that the function of the written description requirement is to ensure that a patent is granted to inventors who had possession, as of the filing date of the application relied on, of the specific subject matter later claimed by them; how the specification accomplishes this is not material. *In re Smith*, 178 U.S.P.Q. 620 (CCPA 1973). Therefore, the test for written description under 35 U.S.C. § 112, first paragraph, is whether the originally filed specification reasonably conveys to any person skilled in the art that Applicants had possession of the subject matter later claimed. *In re Kaslow*, 217 U.S.P.Q. 1089 (Fed. Cir. 1983). [See also, MPEP, Section 2163.02].

Applicants respectfully submit that there is no reasonable basis to assert that the claims must be limited to the specific species disclosed in the specification. The instant invention is not limited to a specific ECL/RC pair. The specific  $\text{Ru}(\text{bpy})_3^{2+}$  - TPA pair disclosed in the specification is provided only as an example of the invention. The original specification broadly describes the terms “electrochemiluminescent label” and “coreactant” on page 6 and discloses an extensive list of useful pairs on pages 13-14. “In claims involving chemical materials, generic formulae usually indicate with specificity what the generic claims encompass. One skilled in the art can distinguish such a formula from others and can identify many of the species that the claims encompass. Accordingly, such a formula is normally an adequate description of the claimed genus” (*Reagents of the University of California v. Eli Lilly*, 119 F.3d 1559, 1568, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997); See also, MPEP 2163 (III-3(a)), page 2100-161, right-hand column).

Furthermore, it is unclear what is the basis for the alleged rejection that “it is not possible to determine the limit of compounds that fall within the scope of these claims because the term ‘coreactant’ encompasses ‘species which are capable of undergoing a chemical transformation to form said interactive species or said precursor species’” (Official Action, pages 9-10).

Applicants urge that the claim limitations are clear and definite when properly construed in view of the specification. The specification clearly provides support for the presently claimed subject matter in compliance with the “written description” requirement of the first paragraph of 35 U.S.C. § 112 and describes the term “coreactant” in the specification, page 6. The specification further describes the term “coreactant” (Specification, Subsection “(A) The coreactant”, pages 9-17). Contrary to the Examiner’s assertion, the term “coreactant” does not encompass “all compounds” when the term is properly construed in view of the specification. Additionally,

claims 3 and 4 have been amended to specify that the coreactant is a material that is oxidized to produce a reductant, or reduced to produce an oxidant.

One skilled in the art would readily recognize from the original disclosure that Applicants invented the presently claimed subject matter. Therefore, Applicants request that this rejection be withdrawn.

**b. Claims 3-4 and 9-22 fully comply with enablement requirement of 35 U.S.C. § 112, first paragraph.**

The subject matter of claims 3-4 and 9-22 has been rejected under 35 U.S.C. § 112, first paragraph, as being enabling for specific disclosed coreactants but allegedly not providing enablement for any coreactant. The Examiner has also alleged that “the preparation and use of coreactants which are present as precursors or species which can be transformed into a coreactant coupled to a generic ECL label do not appear to be within the scope of reasonable experimentation”. (Official Action, page 11).

Applicants respectfully disagree and request that the Examiner reconsider this rejection in the following context. The first paragraph of 35 U.S.C. § 112 requires nothing more than objective enablement. Whether this is achieved by illustrative examples or by broad terminology is of no importance. *In re Marzocchi*, 169 U.S.P.Q. 367 (CCPA 1971). An assertion by the Patent Office that the enabling disclosure is not commensurate with the scope of the protection sought must be supported by evidence or reasoning substantiating the doubt so expressed. *In re Dinh Nguyen*, 181 U.S.P.Q. 46 (CCPA 1974); *In re Brown*, 181 U.S.P.Q. 48 (CCPA 1974); *In re Armbruster*, 185 U.S.P.Q. 152 (CCPA 1975).

As set forth in the specification, the present invention relates to a compound, which comprises an electrochemiluminescent label (EL) linked to a coreactant (CR), which compound emits ECL when exposed to electrochemical energy.

Applicants submit that it is improper to reject claims on the ground that the specification does not support the claims when the terms are no broader than the broadest description of the invention in the specification and there is no reason to challenge the operativeness of the subject matter embraced by the claims. *Ex parte Altermatt*, 183 U.S.P.Q. 436 (POBA 1974). Applicant urges that in order to make a rejection, the Examiner has the initial burden of establishing a reasonable basis to question the enablement provided for the claimed invention. *In re Wright*, 27 U.S.P.Q.2d 1510, 1513 (Fed. Cir. 1993). [See, MPEP § 2164.04]. The Examiner has failed to present any evidence or reasoning substantiating the allegation that the presently claimed subject matter is not enabled. Accordingly, the burden of proving enablement has not shifted to the Applicant and therefore the rejection is improper.

Moreover, Applicants agree that the factors to be considered in determining undue experimentation are those set forth in the case of *In re Wands*, 8 U.S.P.Q.2d 1400 (Fed. Cir. 1988).

As admitted by the Examiner (Official Action, page 12), the relative skill in the art is high. Additionally, at the time of invention, a great deal was known about ECL labels and ECL coreactants. For example, a number of different classes of ECL labels were known in the art at the time of the invention. U.S. Patents Nos. 5,310,687 and 5,643,713, incorporated by reference in the present application, disclose a variety of Ru and Os containing labels (col. 5, line 65 - col. 6, line 15 of the '713 patent) as well as a variety of other types of ECL labels (col. 19, lines 50-60).

Moreover, the present application also describes ECL labels other than Os, Ru and Re complexes. See specifically the list of ECL labels, which contain a metal set forth at pages 23-25 of the specification.

The present application also cites a reference by Knight et al. entitled "Occurrence, Mechanism and Analytical Applications of Electrogenenerated Chemiluminescence", *Analyst*, 119, 879 (1994). Knight lists many additional ECL labels in Table 1 thereby providing an indication of the knowledge and level of skill in the art at the time of the invention with respect to ECL labels. The Knight reference describes some ECL mechanisms believed to be common to large classes of ECL labels. See specifically reactions 1-4, 7-8 and 13-18 cited therein. The Knight reference also describes the criteria that one skilled in the art could use to select appropriate inorganic ECL labels (See last paragraph, page 883).

Preferred ECL labels of the present invention include Ru and Os containing complexes. These compounds are advantageous due to their strong electrochemiluminescence. However, Knight shows that other ECL labels that operate according to similar mechanisms were known and that criteria necessary for selecting other labels were also known. Given the high level of skill in the art as shown by Knight, one skilled in the art would be able to select other labels for use in the compounds of the invention and expect the compounds to function in a similar manner. There is no reasonable basis set forth in the Office Action to support a requirement that the present claims be limited to specific ECL labels disclosed in the application.

The present application also provides enablement for a coreactant which when linked to an ECL label forms a compound that emits ECL when exposed to electrochemical energy. The specification clearly describes the properties of an ECL coreactant "CR" that would guide one skilled in the art towards selecting appropriate moieties (Specification, page 6, lines 13-20). See also page 10, line 18 - page 12, line 25. The application also lists numerous coreactants that can be used in the invention at page 10, lines 5-9 and page 13, line 11 - page 14, line 21. U.S. Patent No. 5,310,687, incorporated by reference on Page 15, line 10 of the specification, describes a



proposed mechanism of the coreactant TPA (page 5, lines 54-67) and also describes how the ability of other molecules to act as coreactants (such as hydrolyzed  $\beta$ -lactams or NADH) can be predicted from similarities in structure to known coreactants such as TPA.

The Knight et al. reference also describes a coreactant in column 1 on page 881 (last paragraph, starting with the language: "A suitable donor or acceptor molecule..."). See also, page 884 in col. 1, in the language set forth after reaction (16) starting at "Alternatively, by the use of strongly oxidizing or reducing species in solution" et seq. Thus, the Knight reference provides an indication of the state of the art of ECL labels and coreactants at the time the present application was filed. The Knight et al. reference, however, does not disclose any advantage to be gained by linking an ECL label with a CR. Nevertheless, one skilled in the art, once in possession of the teachings of the present invention can use the electrochemiluminescent labels and coreactants disclosed in the Knight et al. reference to generate the claimed EL-CR conjugates.

Finally, Applicants submit that enablement is not precluded even where the disclosure requires some experimentation. The test of enablement is not whether any experimentation is necessary, but whether, if experimentation is necessary, is it undue. *In re Angstadt*, 190 U.S.P.Q. 214 (CCPA 1976). [See, MPEP § 2164.01]. The fact that experimentation may be complex does not necessarily make it undue, if the art typically engages in such experimentation. *In re Certain Limited - Charge Cell Culture Microcarriers*, 221 U.S.P.Q. 1165, 1174 (Int'l Trade Comm'n 1983); *MIT. v. A.B. Fortia*, 227 U.S.P.Q. 428 (Fed. Cir. 1985); *In re Wands*, 8 U.S.P.Q.2d 1400 (Fed. Cir. 1988). [See, MPEP § 2164.01]. In fact, a considerable amount of experimentation is permissible. See, *In re Wands*, 8 U.S.P.Q.2d 1400, 1404 (Fed. Cir. 1988). Because the relative skill of those in the art is high, the threshold point at which experimentation becomes undue must

also be high. Given this, Applicants submit that, based on the instant specification, one skilled in the art would not have to engage in undue experimentation in order to practice the invention as claimed. Thus, the specification provides a description sufficient to enable one of ordinary skill in the art to make the claimed invention without undue experimentation.

As long as the specification discloses at least one method for making and using the claimed invention that bears a reasonable correlation to the entire scope of the claim, then the enablement requirement of 35 U.S.C. § 112 is satisfied. *In re Fisher*, 166 U.S.P.Q. 18, 24 (CCPA 1970). [MPEP § 2164.01(b)]. Therefore, there is no need to limit the claims to the specific coreactants disclosed in, for example, the Knight reference or the specification.

Accordingly, Applicants respectfully submit that additional examples of the complexes of ECL labels linked to coreactants are not necessary if the description of the invention itself is sufficient to permit those skilled in the art to make and use the invention [MPEP § 2164]. A patent does not teach, **and preferably omits**, what is well known in the art. *In re Buchner*, 18 U.S.P.Q.2d 1331, 1332 (Fed. Cir. 1991); *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 231 U.S.P.Q. 81, 94 (Fed. Cir. 1986), *cert. denied*, 480 U.S. 947 (1987); *Lindemann Maschinenfabrik GmbH v. American Hoist & Derrick Co.*, 221 U.S.P.Q. 481, 489 (Fed. Cir. 1984). [See, MPEP § 2164.01].

Accordingly, Applicants submit that there is no reasonable basis set forth in the Official Action to support an enablement rejection. Thus, Applicants respectfully request the withdrawal of the rejection of claims 3-4, 7-8, 9-12 and 15-18 under 35 U.S.C. § 112, first paragraph.

**c. Claims 3-4 and 9-22 are definite under the requirements of 35 U.S.C. § 112, second paragraph.**

Claims 3-4, 9-22 have been further rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention.

Applicants believe that there is no basis for such rejection. Terms in the patent claims are not too vague unless they prevent one skilled in the art from understanding, in light of the specification, what is claimed. *Andrew Corp. v. Gabriel Electronics, Inc.*, 6 U.S.P.Q. 2d 2010 (Fed. Cir. 1988); *U.S. v. Teletronics, Inc.*, 8 U.S.P.Q. 2d 1217 (Fed. Cir. 1988); *Specialty Composites v. Cabot Corp.*, 6 U.S.P.Q.2d 1601 (Fed. Cir. 1988).

Applicants respectfully submit that if the scope of subject matter embraced by a claim is clear and if the Applicant has not otherwise indicated that he intends the claim to be of a different scope, then the claim particularly points out and distinctly claims the subject matter which the applicant regards as his invention. *In re Borkowski*, 164 U.S.P.Q. 642 (CCPA 1970); *In re Robins*, 166 U.S.P.Q. 552 (CCPA 1970). Breadth alone is not indefiniteness. *In re Gardner*, 166 U.S.P.Q. 138 (CCPA 1970); *In re Conley*, 180 U.S.P.Q. 454 (CCPA 1974); *Ex parte Lewis*, 197 U.S.P.Q. 543 (Bd. App. 1977).

A fundamental principle contained in 35 U.S.C. § 112, second paragraph, is that Applicants are their own lexicographers. Applicants can define in the claims what they regard as their invention essentially in whatever terms they choose so long as the terms are not used in ways that are contrary to accepted meanings in the art. Applicants may use functional language, alternative expressions, negative limitations, or any style of expression or format of a claim which makes clear the boundaries of the subject matter for which protection is sought (MPEP § 2173.01). A claim may not be rejected solely because of the type of language used to define the

subject matter for which patent protection is sought. *In re Swinehart*, 160 U.S.P.Q. 226 (CCPA 1971).

Applicants respectfully submit that the Examiner's focus during the examination of claims for compliance with 35 U.S.C. § 112, second paragraph, is whether the claims meet the threshold requirements of clarity and precision, not whether more suitable language or modes of expression are available (MPEP § 2173.02).

Applicants urge that the definiteness of claim language must be analyzed, not in a vacuum, but in light of (1) the content of the particular application disclosure, (2) the teachings of the prior art, and (3) the claim interpretation that would be given by one possessing the ordinary level of skill in the pertinent art at the time the invention was made (MPEP § 2173.02). Applicants urge the claims fully meet the requirements of 35 U.S.C. § 112, second paragraph.

More specifically, the definition of "coreactant" on page 6 is limited to reactants that can be linked to an ECL label to form an ECL compound that emits ECL when exposed to electrochemical energy. Moreover, the description of coreactant on page 6 is also supplemented with a great deal of detail on pages 9 to 17 of the specification. Finally, Applicants have amended claim 3 and 4 to further define the present invention.

The Examiner has also found the term "linked" to be vague and indefinite. The term "linked" is based on the fact that there is a linkage between CR and EL. Linkage has been described in great detail starting at page 17, line 8 to page 21, line 9 of the specification. In view of the very detailed description of linkage in the specification and the level of skill in this highly developed art, Applicants urge that, the term "linked" is neither vague nor indefinite. Thus, the rejection based on 35 U.S.C. § 112, second paragraph, is inappropriate and should be withdrawn.

**d. Claims 3-4, 10, 12-13 and 18-22 Are Novel Under 35 U.S.C. § 102(a) Over Liang et al.**

Applicants urge that Liang et al. is not a prior art under 35 U.S.C. § 102(a). The present specification claims priority to June 7, 1995, the filing date of parent application Serial No. 08/485,419 (now U.S. Patent No. 5,643,713 to Liang et al. issued July 1, 1997) and therefore claims 3-4, 10, 12-13 and 18-22 are entitled to a priority date of June 7, 1995. Therefore, the cited article by Liang et al., published in 1996, is not available as prior art under 35 U.S.C. § 102(a).

Therefore the rejection of claims 3-4, 10, 12-13 and 18-22 under 35 U.S.C. § 102(a) is improper and should be withdrawn.

**e. Claims 3-4, 11, 13 and 14 Are Novel Under 35 U.S.C. § 102(b) Over Faulkner LR.**

Applicants urge that the subject matter of claims 3-4, 11, 13 and 14 is not anticipated by Faulkner LR. The Examiner alleges that the dimethylaniline moiety of the compound of Itaya and Toshima acts as a coreactant. Applicants do not concede this point, but even assuming the Examiner is correct, the compound of Itaya and Toshima would be expected to require oxidation of the luminophore and concurrent reduction of the dimethylamine moiety to provide a strong reductant (see the mechanism on page 507 of the Faulkner reference). By contrast, the coreactants of amended claims 3 and 4 require a co-reactant that undergoes oxidation to form a reductant or reduction to form an oxidant. (See, Claims 3 and 4). This property allows for the formation at an oxidizing electrode of both an oxidized ECL label and a strong reductant (or alternatively, the formation at a reducing electrode of both a reduced ECL label and a strong oxidant).

Applicants submit that Faulkner LR does not anticipate the presently claimed subject matter. "A claim is anticipated only if each and every element as set forth in the claim is found,

either expressly or inherently described, in a single prior art reference” *Verdegaal Bros. V. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). “The identical invention must be shown in as complete detail as is contained in the...claim”. *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). (See, MPEP § 2131).

Moreover, there is no reasonable basis to support an assertion that the compounds of Faulkner “inherently” fall within the scope of the claims. The mechanistic description in Faulkner, in fact, provides evidence to the opposite. In order to make a rejection based on “inherency”, the Examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristics **necessarily** flow from the teachings of the prior art. *Ex parte Levy*, 17 U.S.P.Q. 2d 1461 (B.P.A.I. 1990). The fact that a prior art article may inherently have the characteristics of the claimed article is not sufficient. *Ex parte Skinner*, 2 U.S.P.Q. 2d 1788 (B.P.A.I. 1986). Inherency **must be a necessary result** and not merely a possible result. *In re Oelrich*, 212 U.S.P.Q. 2d 323 (CCPA 1981); *Ex parte Keith*, 154 U.S.P.Q. 320 (P.O.B.A. 1966). To establish inherency, the extrinsic evidence “must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill.” *In re Robertson*, 49 U.S.P.Q. 1949, 1950-51 (Fed. Cir. 1999) [citing *Continental Can Co. v. Monsanto Co.*, 20 U.S.P.Q.2d 1726, 1749 (Fed. Cir. 1991)]. The Examiner's attention is directed to MPEP § 2112.

Accordingly, claims 3-4, 11, 13 and 14 are not anticipated by Faulkner LR. Therefore the rejection under 35 U.S.C. § 102(b) is improper and should be withdrawn.

**f. Claims 3-4, 10-14, and 19-22 Are Novel Under 35 U.S.C. § 102(b) Over Massey WO 87/06706.**

Claims 3-4, 10-14, and 19-22 have been rejected under 35 U.S.C. § 102(b) as being anticipated by Massey WO 87/06706 (‘706). More specifically, the Examiner alleges that on

pages 144, 189 and 193, that Massey ('706) discloses  $\text{Ru}(\text{bpy})_3$ , digoxigenin and theophylline linked to  $\text{Ru}(\text{bpy})_3^{2+}$  which meets the limitations of the claim. Applicants respectfully disagree.

Massey ('706) does not disclose the presently claimed compounds. The digoxigenin and theophylline as disclosed on pages 189 and 193 of the cited reference are the analytes of interest, not the coreactants or the chemically transformable first compounds as defined in the Applicants' specification at page 6, line 13 et seq. These compounds are used to bind another entity such as an antibody with which it forms a complex. As such, digoxigenin and theophylline do not play a role in the actual emission of ECL and can not be considered a "coreactant" as defined in claims 3-4, 10-14, and 19-22.

Furthermore, the disclosure of  $\text{Ru}(\text{bpy})_3$  linked to  $\text{Ru}(\text{bpy})_3$  also fails to anticipate the claimed invention (page 144). Massey ('706) does not teach or suggest that one of the  $\text{Ru}(\text{bpy})_3$  molecules may work as a coreactant for another  $\text{Ru}(\text{bpy})_3$  molecule. On the contrary, it appears that both  $\text{Ru}(\text{bpy})_3$  molecules are at the same oxidation state (Massey, '706, page 144) and thus do not result in an ECL label/coreactant pair. Therefore, the disclosure of Massey does not anticipate all claim limitations of the present invention.

Finally, the description in Massey ('706) relates to complexes where both the ECL label  $\text{Ru}(\text{bpy})_3$  molecules are linked to an analyte of interest (digoxigenin) and not to each other, as described in the specification and set forth in the claims.

Therefore, the rejection based on the Massey ('706) reference under 35 U.S.C. § 102(b) is inappropriate and should be withdrawn.

**g. Claims 3-4, 10-14 and 19-22 Are Novel Under 35 U.S.C. § 102(e) Over Massey et al. U.S. Patent No. 5,591,581 ('581).**

Claims 3-4, 10-14 and 19-22 have also been rejected under 35 U.S.C. § 102(e) as being unpatentable over the '581 Massey patent. More specifically, the Examiner alleges that the '581

Massey patent discloses ECL labels with a coordinated Re atom linked to numerous B compounds where B can be peptides, nucleic acids, polysaccharides and other moieties recited in claim 1 of the '581 patent.

Applicants respectfully disagree. The '581 Massey patent does not anticipate the claimed invention. More specifically, the '581 Massey patent does not disclose B as a "coreactant" or a precursor species or species which undergoes a chemical transformation and thereafter interacts with an ECL label to produce ECL.

Furthermore, the amines cited by the Examiner in the '581 patent (e.g., col. 15, lines 1-15 and col. 30, line 38- col. 31, line 37) are part of the compound and are not disclosed as coreactants as defined in the Applicants' specification at page 6, line 13 et seq. Contrary to the Examiner's assertion, the amines bounded to the Re in the '581 patent are not coreactants as defined by the Applicants' specification, but are part of the Re label compound itself. Re by itself is not a label and will not emit light (i.e., will not luminesce). Re must be part of an organometallic complex in order to be an ECL label which emits light (i.e., luminesce). The amines disclosed in the '581 Massey patent allow for better ligand binding to the Re to form the organometallic complex ECL label compound. If these amines were oxidized or reduced (as would occur with a coreactant) it would in effect destroy the photophysical ECL properties of the Re-containing ECL complex - this is contrary to the function of a coreactant.

In order to have a valid rejection under 25 U.S.C. § 102, all the elements of the rejected claims must be disclosed in the cited reference. To the extent that a CR linked to an EL is not disclosed, the '581 patent cannot anticipate the claims. Accordingly, this rejection is inappropriate and should be withdrawn.



**h. Claims 3-4, 10-14 and 19-22 Are Novel Under 35 U.S.C. §§102(f) and (g) Over '581 Massey patent.**

Claims 3-4, 10-14 and 19-22 have also been rejected under 102(f) and 102(g) as allegedly being unpatentable over the '581 patent to Massey et al. Additionally, the Examiner also rejected claims 3-4, 10-14 and 19-22 as allegedly not being patentably distinct from claim 1-6 and 20 of the '581 patent. Specifically, the Examiner requests a showing that the conflicting inventions were commonly owned at the time of the invention of this application. Applicants hereby state that these inventions were all commonly owned at the time of the invention of this application.

As with the Liang reference, Applicants have already submitted during the prosecution of the parent application (Amendment mailed December 22, 1999, Appendix A) copies of an executed Employee Proprietary Information Agreement evidencing the fact that the inventions were commonly assigned. Assuming arguendo that the subject matter of the '581 patent might otherwise qualify as prior art under 35 U.S.C. § 102(f) or (g), which it does not, the patentability of the subject matter of the claims of the present application is not precluded, because the inventors of the '581 patent and the present application were at the relevant time owned by the same entity or subject to an obligation of assignment to the same entity.

Moreover, Applicants direct the Examiner's attention to that fact that application No. 08/227,898, which issued as U.S. Patent No. 5,591,581, has been commonly owned by the same entity, namely IGEN International Inc. More specifically, an Assignment for the 08/227,898 application has been recorded on January 25, 1988 on Reel 4878/Frame 0008.

Accordingly, Applicant submits the rejection is improper and should be withdrawn.

**i. Claims 3-4, 9-17, 19 and 21-22 Are Not Obvious Under 35 U.S.C. § 103(a) Over Knight et al. in View of Faulkner LR.**

Applicants urge that the present invention is not obvious over the disclosure of Knight et al., alone or in combination with Faulkner LR.

The Examiner admits that Knight et al. “does not teach the advantage of linking an EL with a CR” (Official Action, page 21).

Applicants urge that Faulkner LR does not compensate for the deficiencies of Knight et al. because Faulkner does not teach or suggest the presently claimed subject matter (as discussed, supra, in section IV.e). Faulkner does not teach or suggest that the coreactant of the cited compound can undergo oxidation to form a reductant, or reduction to form an oxidant. On the contrary, there is no reasonable basis to assert that the cited compound will have such oxidation/reduction properties. Therefore, a person of ordinary skill in the art would not find a reasonable suggestion or motivation to combine the teaching of electrochemically excitable compounds of Knight with the label-coreactant linkage of compounds of Faulkner.

Therefore, the rejection of claims 3-4, 9-17, 19 and 21-22 under 35 U.S.C. § 103(a) over Knight et al. in view of Faulkner LR is improper and should be withdrawn.

#### **V. “Double Patenting”**

The rejection of claims 3-4 and 9-22 under the judicially created doctrine of double patenting over claims 1-6 and 19-20 of the commonly assigned ‘581 Massey patent and over claims 1-6 of the commonly assigned Liang ‘713 patent is believed to be unwarranted.

The doctrine of double patenting functions to preclude the same inventor or assignee from extending the statutory patent term via securing of a second patent on the same invention or an obvious variant thereof. The focus of any double patenting analysis is on the claims in the patents or patent applications involved. MPEP § 804.


The present claims are not rendered obvious in view of the claims of the ‘581 patent of Massey et al. for the reasons set forth above. The present claims relate to compounds comprising

ECL labels linked to co-reactants, wherein the compounds are capable of emitting ECL. The claims of the '581 Massey patent do not teach or suggest the presently claimed subject matter.

Accordingly, Applicants urge that the rejection of claims 3-4 and 9-22 under the judicially created doctrine of obviousness-type double patenting over the claims of the '581 patent is improper and its withdrawal is respectfully requested.

With respect to a terminal disclaimer regarding the '713 patent of Lang et al., Applicants respectfully request that this be held in abeyance until the claims are held allowable. Applicants will consider the submission of the terminal disclaimer upon the allowance of the claims.

By:



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